



COMMONWEALTH OF VIRGINIA
Department of Health

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**FINDINGS, DISCUSSION AND RECOMMENDATION
TO THE STATE HEALTH COMMISSIONER
REGARDING CERTIFICATE OF PUBLIC NEED (COPN)
REQUEST NUMBER VA-6635,
VIRGINIA IMAGING, LLC
d/b/a HEART IMAGING CENTER OF VIRGINIA
RICHMOND
ESTABLISHMENT OF A MEDICAL FACILITY TO PROVIDE
ELECTRON BEAM TOMOGRAPHY (EBT),
A FORM OF COMPUTED TOMOGRAPHY (CT)**

A. FINDINGS OF FACT

1. In October 2001, Virginia Imaging, L.L.C., a Virginia limited liability company, applied for a certificate of public need (COPN). Virginia Imaging's application seeks authorization to establish a freestanding medical facility to provide electron beam tomography (EBT), a form of computed tomography (CT). The total capital and financing costs of the proposed project is \$2,505,820.
2. EBT is a specialized, proprietary technology, marketed by Imatron, Inc., headquartered in South San Francisco, California. Imatron holds a patent on EBT technology and recently merged with GE Medical Systems, a unit of General Electric Company.
3. EBT accomplishes scanning speeds significantly greater than conventional CT technology. EBT presents the ability to create precise images of the human heart through a procedure known as a coronary artery scan (CAS). This procedure allows quantification of calcium in the coronary arteries of asymptomatic patients at risk for coronary atherosclerosis, thereby carrying the potential to detect cardiac disease, a major cause of death in the U.S., early in its development.
4. Virginia Imaging has offices located in Henrico County, in a medical office building on the campus of Bon Secours St. Mary's Hospital. Virginia Imaging would conduct business as the Heart Imaging Center of Virginia in a medical office building located in Henrico County, west of the City of

Richmond. Henrico County is within Planning District (PD) 15 and Virginia's Health Planning Region IV. PD 15 includes the City of Richmond and the counties of Charles City, Chesterfield, Goochland, Hanover, Henrico, New Kent and Powhatan.

5. Virginia Imaging is organized as a Virginia limited liability company (LLC) that is wholly owned by VCS Properties, LLC, and Syncor Cardiology Services, LLC. VCS Properties, in turn, is wholly owned by Virginia Cardiovascular Specialists, PC, a specialized medical group with 34 physician-members. Syncor Cardiology Services is wholly owned by Syncor International Corporation, which has offices in Woodland Hills, California.

6. The Central Virginia Health Planning Agency (CVHPA) serves HPR IV by reviewing "projects," as defined in Section 32.1-102.1 of the Virginia Code, proposed for location within the boundaries of HPR IV.

7. Sections 32.1-102.1 and 32.1-102.3 of the Code of Virginia require that a project proposing the establishment of a "medical care facility," which includes a "[s]pecialized center[] or clinic[] . . . developed for the provision of . . . computed tomographic (CT) scanning . . . [among other things]" must be approved by the State Health Commissioner through issuance of a COPN.

8. Virginia regulation, *viz.*, Part II of Chapter 320 of the State Medical Facilities Plan (SMFP) 12 VAC 5-320-20 *et seq.*, contains standards and provisions with which the Commissioner may review applications for the establishment of specialized centers and equipment for providing CT services.

9. Virginia regulation, *viz.*, 12 VAC 5-32-10, defines "[c]omputed tomography (CT)" to mean "the construction of images through the detection and computer analysis of numerous X-ray beams directed through a part of the body."

10. According to a February 2000 "expert consensus document" on EBT prepared by the American College of Cardiology and the American Heart Association, EBT is "a highly sensitive technique for detecting coronary artery calcium and is being used with increasing frequency for the screening of asymptomatic people to assess those at high risk for developing coronary heart disease (CHD) and cardiac events, as well as for the diagnosis of obstructive coronary artery disease (CAD) in symptomatic patients." This document also recommends, however, that EBT not be used as a screening tool in asymptomatic patients without multiple risk factors because its widespread use could result in a high percentage of false positive results and unnecessary, costly additional tests.

11. In its report on Virginia Imaging's application, CVHPA relied in part on an assessment of EBT performed by ECRI (formerly the Emergency Care Research Institute), an independent, nonprofit research agency, with a focus on, among other things, healthcare technology. ECRI believes that EBT may provide valuable information in treating "a limited population," including certain asymptomatic and symptomatic patients. ECRI observes that the cost of an EBT scan is reimbursed by many insurers when a physician has made a referral based on medical indication, but that reimbursement for general CAD screening "is highly unlikely . . . despite public demand." ECRI believes further that greater use of EBT may increase health care costs insofar as the number of patients receiving additional diagnostic tests, treatment procedures and drug therapy would likely increase. ECRI advocates additional studies to determine the clinical and cost effectiveness of EBT.

12. In an article in the November 2001 issue of the Journal of Clinical Outcomes Management (JCOM), Matthew J. Budoff, M.D., of Harbor-UCLA Medical Center, observes that
[g]iven the burden of . . . [CAD], accounting for over 500,000 deaths annually, there is a need for new strategies for identifying high-risk individuals prior to the first [cardiac] event. . . . Calcific deposits in coronary arteries are pathognomonic of atherosclerosis. . . . [EBT's r]apid image acquisition prevents image blurring and allows accurate visualization of very small calcium deposits in the coronary arteries. . . . The use of EBT to better risk stratify patients *could greatly reduce costs and better direct therapy* [Emphasis added].

Dr. Budoff also observes that scanning the heart and coronary arteries using generally-available spiral CT will never produce the accuracy and detail of EBT scanning and that employing spiral CT for such purpose potentially involves administering radiation doses to the patient six to 38 times greater than that administered by EBT.

13. Overall, the literature in the record regarding this matter suggests that EBT holds considerable benefit for effectively diagnosing inchoate, but serious, disease.

14. According to statistics compiled by the Virginia Department of Health, Center for Health Statistics, over one-third of all reported deaths in Virginia resulted directly from heart disease in 1999.

15. Virginia Imaging asserts that

EBT does something that conventional diagnostic CT scanners cannot reliably do. The purpose of EBT is to image and quantify calcium in the coronary arteries of people before they develop symptoms of disease. Since calcium is highly correlated with plaque burden, calcium scoring is able to very effectively identify patients at risk for sudden death from myocardial infarction. . . . This means that patients with coronary artery disease can be treated earlier – before symptoms occur – when treatment is most effective. And for some patients, if calcium is absent, calcium scoring is able to rule out coronary artery disease altogether. . . . This means that some patients who would otherwise have been treated can avoid expensive or invasive medical treatments.

Further, Virginia Imaging observes that

[o]nly EBT has been shown to accurately measure the volume and the distribution of calcium of the coronary arteries. Only EBT has been approved by the FDA for cardiac calcium scoring. . . . Other imaging systems, including conventional CT scanners, have been evaluated in the diagnosis of cardiac disease, but their application is extremely limited because of image degradation, artifacts, and distortions arising from the heart's motion as it beats. The fast scanning speed of the EBT scanner allows it to “freeze” the motion of the beating heart in order to image and quantify small calcium deposits in the coronary arteries. . . . As a result, EBT images are sharp and free of motion-related artifacts. Conventional CT scanners cannot do this.

16. Currently, PD 15 has at least 21 hospital-based CT scanners and four CT scanners in freestanding facilities. Several of these scanners have available capacity, indicating a surplus of CT services in PD 15. The Richmond area, however, has an advanced tertiary system of open heart surgery services and invasive cardiovascular programs that may benefit from the ready availability of EBT services. The Commonwealth presently has no EBT equipment or facility.

17. The CVHPA has recommended denial of the application, based in part on the existence of sufficient CT capacity and services in PD 15, as discussed below.

18. By letter dated January 22, 2002, the Virginia Department of Health, Division of Certificate of Public Need (DCOPN) notified Virginia Imaging that DCOPN recommends denial of the application to establish a facility providing EBT services.

19. An IFFC was convened on January 29, 2002, in Richmond pursuant to Sections 2.2-4019 and 32.1-201.6 of the Virginia Code to discuss this application.

B. DISCUSSION

Section 32.1-102.3 B of the Code of Virginia requires that, in determining whether a public need for a proposed project has been demonstrated, the State Health Commissioner shall review an application for a certificate of public need in relation to the twenty considerations enumerated in that section. The following is a discussion of the application in relation to these considerations.

1. The recommendation and the reasons therefor of the appropriate regional health planning agency.

The Board of Directors of CVHPA voted 12 to seven, with one abstention, to recommend denial of Virginia Imaging's application to establish to establish a facility providing EBT services. CVHPA based its recommendation on the following considerations:

- (i) There are existing providers in relatively close proximity who have not met the SMFP threshold standards. Moreover, freestanding diagnostic imaging CT services are marginally utilized throughout the planning district;
- (ii) The proposal would not improve or would only marginally improve financial or geographic access to CT services;
- (iii) There are other reasonable alternatives to the proposal;
- (iv) There is not a public need for these projects. If there were a need for additional capacity, given the utilization levels of CT services at hospitals, it would be more reasonable and cost effective to add these services to highly utilized providers.

2. The relationship of the project to the applicable health plans of the regional health planning agency, the Virginia Health Planning Board and the Board of Health.

The applicable health plan is Part II of Chapter 320 of the State Medical Facilities Plan (SMFP), found at 12 VAC 5-320-20 *et seq.* (Text appearing under this consideration in italics has been selected from the SMFP and precedes discussion of the proposed project in relation to the selected text.)

The application raises no particular issues in relation to the SMFP provisions addressing acceptability and geographic accessibility. Circumstances, however, complicate the ability to conclude that the proposed project will comply with the SMFP provision addressing financial accessibility, *i.e.*, the requirement that the proposed service be accessible to patients needing such service “without regard to their ability to pay or the payment source.”

Virginia Imaging states that

it will strive to provide charity care and meet whatever standards are established for treatment and diagnosis of patients who lack the resources to pay for EBT scanning services. While the service will initially operate as a private pay service, it is expected that third party insurers will begin to provide coverage once the value of this technology is accepted in the market. Indeed, in other markets where EBT has become available, insurance companies have begun to cover scans, recognizing the cost savings involved in better diagnoses. . . . Additionally, [Virginia Imaging] intends to actively seek out and provide care to patients who lack the resources to pay for scans.

In its rebuttal submission, Virginia Imaging represented further that it has

[d]eveloped an indigent care policy and has proposed to undertake efforts to work with existing providers of community outreach programs to assure that patients who lack the means to pay for cardiac scans are not denied care on that basis. . . . [Virginia Imaging] proposes to provide free or reduced price care at a level that exceeds the median level of hospital charity care provided in . . . [PD 15] in 1999.

In 1999, the median level of hospital charity care for HPR IV was 0.7 percent, expressed as a percentage of gross patient revenue. Charity care conditions placed on the issuance of a COPN pursuant to Virginia Code Section 32.1-102.2 C are typically gauged to the HPR median.

12 VAC 5-320-50. Need for New Service. A. Preference will be given to proposals involving the provision of full-body CT scanning rather than units which can perform only CT head scans.

Since Virginia Imaging’s application is not competing with another, this provision does not apply and the attendant operation of a preference is not warranted; however, Virginia Imaging’s proposed project would include the capability of providing full-body CT scanning.

B. No CT service should be approved at a site which is within 30 minutes driving time of: (i) a COPN approved or exempted CT service that is not yet operational; or (ii) an existing CT unit that has performed fewer than 3,500 HECTs or 3,000 combined CT head and body scans during the relevant reporting period.

C. A proposed new CT service may be approved if . . . in the case of a proposed non-hospital-based service, the applicant demonstrates that the number of outpatient studies performed by other CT services on the applicant's patients during the relevant reporting period is at least 3,500 HECTs or 3,000 combined CT head and body scan.

D. No new, non-hospital-based CT service or network may be approved unless all existing CT services or networks in the planning district, whether hospital-based, non-hospital-based, mobile or fixed, performed an average of at least 5,000 HECTs or 4,500 combined CT head and body scans per machine during the relevant reporting period.

Twenty-five CT scanners are operational in PD 15. Twenty-one of these are located at general hospitals and four are located at freestanding outpatient centers. Three of the scanners located in hospitals perform fewer than 5,000 HECTs annually and nine hospital-based scanners performed fewer than 4,500 CT scans. Four non-hospital outpatient centers, including Bon Secours Imaging Center at Chesterfield, Hanover Outpatient Center, MCVH's facility at Stony Point, and Virginia Physicians at Stony Point, each have a single CT scanner. With the exception of the last, all of the scanners in freestanding centers perform fewer than 4,500 scans annually.

Hospital-Based CT Inventory and Utilization in PD 15

Facility	Number of CT Units	Number of Scans Per Scanner	Number of HECTs Per Scanner
Bon Secours Memorial Regional Medical Center	4	2,982	5,666
Bon Secours Richmond Community Hospital	1	1,627	2,576
Bon Secours St.Mary's Hospital	2	7,319	7,319
Bon Secours Stuart Circle Hospital	1	2,762	4,771
Capitol Medical Center*	1	1,356	1,978
CJW-Chippenham Medical Center	2	7,330	11,228
Henrico Doctors' Hospital (Parham Road)	1	3,176	6,095
Henrico Doctors' Hospital (Forest)	2	7,940	12,354
CJW-Johnston-Willis Medical Center	2	7,654	11,930
Medical College of Virginia Hospitals (MCVH)	5	5,389	8,248
Retreat Hospital	1	3,869	5,992
<i>PD 15 Total and Average</i>	22	4,673	7,105

* Closed

The availability of unused CT capacity in PD 15 results in the recognized failure of the proposed project to comply with the availability provisions of the SMFP, set out above. These provisions, however, taken by themselves and without resort to other considerations, would effectively prevent the introduction of progressive and innovative technologies, such as EBT.

The specific technology and planned purpose of Virginia Imaging's EBT project involves creating precise images of the heart as an advancement in the early determination of coronary disease. The technology underlying an EBT scanner clearly falls within the regulatory definition of CT, and therefore, requires the technical placement of an EBT scanner in the inventory of CT scanners within a PD. The overall health system may not be well served, however, by considering an EBT scanner as fully interchangeable with conventional CT scanners, which involve similar technology employed for general diagnostic purposes, and concluding that an existing surplus of CT capacity requires denial of the Virginia Imaging project.

Approval of the proposed project appears highly unlikely to suppress utilization of existing CT scanners in PD 15, or to increase their cost of operation, since the purpose of the proposed project consists of providing a service distinguishable from the general diagnostic role of existing CTs and heretofore not offered anywhere in Virginia. The very fact that the technology underlying and the purpose driving the proposed EBT service is not interchangeable with general CT scanners, along with the considerable benefits to public health that would likely accrue from the precise imaging introduction of EBT would bring, warrant consideration of the project in a broader sense that counsels against denial based on a rigid application of the SMFP's availability standards, set out above.

12 VAC 5-320-80. Coordination of Service. Providers of CT services should provide courtesy privileges to qualified physicians for use for their patients who are expected to be treated on an outpatient basis.

Virginia Imaging intends to make the proposed EBT scanning services available to all physicians and patients in the greater Richmond area. Virginia Imaging expects primary care physicians and cardiologists to recognize the value in using EBT scanning to inform the diagnosis of patients. Virginia Imaging has proffered letters of support from competing cardiology groups and primary care physicians.

12 VAC 5-320-90. Cost and charges. The total costs (direct and indirect) for providing CT services should be comparable to other similar service providers in the planning district.

According to Virginia Imaging, the average cost per procedure for a coronary artery scan (CAS) by the EBT scanner would be \$322 in 2002 and \$495 in 2003. The average charge for an EBT scan would be \$495 per scan in the first and second years of operation.

This charge compares favorably to the charges levied by existing providers of diagnostic CT scans in PD 15, which ranges from \$704 to \$1,334. Since the EBT procedure differs in purpose and in technical aspect from a diagnostic CT procedure and since reimbursement of the charge for an EBT scan has not yet been generally established, comparing the projected charge to charges for existing CT services is not necessarily helpful in determining the appropriateness of the charge projected by Virginia Imaging or in gauging the issue of patients' financial accessibility to the service. Regardless, the intended charge appears reasonable in light of the benefits EBT scanning holds for diagnosing inchoate, but serious, disease.

12 VAC 5-320-100. Staffing. A. Providers of CT services should be under the direct, on-site supervision of one or more physicians with documented formal training in the production and interpretation of cross-sectional computed tomography images. B. CT services should be staffed by qualified and experienced technologists consistent with the types and volumes of computed tomography services offered.

The EBT service proposed by Virginia Imaging would be under the direct supervision of an identified board-certified cardiologist.

12 VAC 5-320-110. Space. A. Applicants for certificates of public need should document to the satisfaction of the Department that (i) an appropriate environment will be provided for the proposed

CT services, including protection against radiant energy and other known hazards; (ii) adequate space will be provided for patient waiting, patient preparation, staff and patient bathrooms, staff activities, storage of records and supplies, and other space necessary to accommodate the needs of handicapped persons.

Virginia Imaging states that the EBT scanner and service would be located in a currently-existing, appropriately-designed office suite that has adequate space for patient and staff areas.

B. Applicants for certificates of public need should document to the satisfaction of the Department that the proposed CT service's physical relationship to the applicant's other diagnostic imaging services will be logical and practical with respect to transportation and staff activity patterns.

This provision is not applicable insofar as the applicant has no regulated diagnostic imaging services with which the proposed service would be coordinated.

3. The relationship of the project to the long-range development plan, if any, of the person applying for a certificate.

Virginia Imaging does not have a formal long-range development plan; however, this project is consistent with the growth of the cardiology group associated with the applicant and with Syncor's goals and mission.

4. The need that the population served or to be served by the project has for the project, including, but not limited to, the needs of rural populations in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.

Virginia Imaging envisions a "service area of about a million people," which is an apparent reference to a geographical area comprising most of HPR IV, which includes PDs 13, 14, 15 and 19 and had a total population of 1,218,327 in 2000, according to the U.S. census. The percentage of persons living below the federal poverty level in HPR IV is 13.9 percent, and the number of African-Americans in HPR IV was 394,459 – or over 32 percent – in 2000.

The proposed project would be located in PD 15, which includes the counties of Charles City, Chesterfield, Goochland, Hanover, Henrico, New Kent and Powhatan and the City of Richmond. PD 15 had a population of 865,941 in 2000. Projections suggest that this total will increase by 7.3 percent by 2005, to an estimated total of 929,000. Based on demographic data, Virginia Imaging estimates that the number of persons between the ages of 40 and 64 in PD 15 was 589,808 in 2000. These persons, Virginia Imaging believes, stand to benefit most from the proposed EBT service's promise in detecting coronary artery disease early. Reliable indications suggest that this age group is one of the fastest growing segments of the population in PD 15 and elsewhere.

As proposed, the project would depend entirely on self-paying patients, since no clearly-established public or private reimbursement mechanisms presently exist for EBT scanning. The charge per scan would be \$495. As proposed, the project runs a substantial risk of being financially unavailable to a large segment of the population, including African-American males, many of whom may be indigent and who statistically carry a considerably higher risk of coronary artery disease than

the general population, and others, who are indigent. Despite the innovative application of technology this project constitutes, without some affirmatively-designed mechanism to promote financial accessibility among *all* persons who have demonstrable medical indication of needing the very service Virginia Imaging proposes, the proposal would be manifestly unapprovable.

Since African-American males carry a substantial risk of coronary heart disease, ensuring their access and the access of indigent persons in HPR IV to this technology and service is vital to serving the public need. If African-American males constitute half of the total percentage of HPR IV residents who are African-American, they would constitute about 15 percent of the HPR's population. This figure is close to the percentage of indigent residents in HPR IV, *i.e.*, 13.9 percent, although no assumption that the two segments of the population overlap substantially would be accurate or necessary. In essence, based on Virginia Imaging's agreement to the charity care and primary care condition set forth in the attachment to this recommendation, I deem the project, *in toto*, to be generally approvable despite the ostensible conclusion, reached through applying the SMFP's availability standards, that no additional CT capacity is needed in PD 15.

In order to avoid denying the intended service area, and, indeed, Virginia in its entirety, a technologically-innovative service that holds considerable promise, I recommend that any COPN issued to Virginia Imaging authorizing the proposed project contain the condition in the attachment, which is designed to impose a unique, appropriate and verifiable charity and primary care obligation, as authorized by Virginia Code Section 32.1-102.2 C. This condition and the set of obligations it creates have been developed through negotiation with Virginia Imaging.

The General Assembly amended Virginia Code Section 32.1-102.3 B in 1999 to include the latter phrasing in the fourth statutory consideration, set out above, directing special attention to "the needs of rural populations in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care" (as well as similar phrasing in the sixth, ninth and nineteenth statutory considerations, below). *See Acts of Assembly, c. 926, 1999.* Many residents of the southern portion of HPR IV live in rural areas, many are indigent, and over 32 percent of the population of HPR IV are African-American. This statutory amendment and these considerations counsel approval of this project and further underscore the need for an affirmative mechanism to promote financial access to EBT services in HPR IV and the Commonwealth, as would be attempted in carrying out the charity and primary care condition in the attachment in the event Virginia Imaging's project meets approval.

5. The extent to which the project will be accessible to all residents of the area proposed to be served.

Virginia Imaging's EBT scanner will be located in offices denoted as the Heart Imaging Center of Virginia, in the Highlands II medical office building on Forest Avenue, just west of the City of Richmond. This location in western Henrico County would be convenient to many patients and physicians in the immediate area, and is accessible by public transportation. It is near Henrico Doctors' Hospital and Bon Secours St. Mary's Hospital, and is within a few miles of Interstate 64, Glenside Avenue and Broad Street, which also serves as U.S. Route 250.

As discussed above, the absence of any established structure of reimbursement for EBT services would render the project infeasible but for self-paying patients. Its accessibility to members of the general population, particularly socio-economically stressed demographic groups that appear to exhibit greater incidence of heart disease, would be severely limited unless a structure for affirmatively requiring charity care, as discussed above, conditions issuance of a COPN for this proposal.

6. The area, population, topography, highway facilities and availability of the services to be provided by the project in the particular part of the health service area in which the project is proposed, in particular, the distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.

Virginia Imaging identifies a service area that roughly corresponds to HPR IV. The proposed project would be located in western Henrico County, in PD 15, which contains numerous open heart surgical programs and cardiac catheterization laboratories. Currently, patients who wish to have an EBT scan must travel outside Virginia. Approval of this project would make EBT scanning services more geographically accessible to the area population, although financial accessibility would remain an issue in the event that an effective program to ensure charity care is not required and implemented.

7. Less costly or more effective alternate methods of reasonably meeting identified health service needs.

If the proposed project is viewed only as introducing another CT scanner to the existing inventory, the less costly alternative would involve its denial, as PD 15 already has a surplus of CT capacity. If, however, the unique capabilities of the proposed EBT scanner become operative in the decision whether to approve it, then no alternatives present themselves.

Virginia Imaging observes that

[t]raditional methods of detecting cardiac disease are not as effective, especially at earlier stages of the disease, and do not provide the treating physician with the same kind of detailed information that EBT does. . . . [O]nly recently [have] physicians . . . learned to effectively use and interpret the significant amount of information provided by an EBT scan. The scans have shown themselves to be extremely reliable and effective in guiding the diagnosis and treatment of patients with cardiac disease. Other technologies still have their use in the diagnosis and treatment of cardiac disease, but none has [sic] shown itself to be as effective at the detection and quantification of early cardiac disease as EBT. Armed with the information provided by EBT, physicians can confidently plan a course of treatment specifically tailored to the patient's condition, sometimes avoiding the need for invasive treatments or expensive courses of medication. In the markets where it has been used, EBT has shown itself to be an important component in the fight against cardiac disease.

Regarding cost, Virginia Imaging notes that

EBT is not more expensive than other types of cardiac testing, nor does it carry the same level of risk. In fact, EBT scanning is among the least expensive of the cardiac testing

modalities and it carries with it far less radiation exposure than even traditional CT exams. Yet it is more effective in identifying early stage cardiac disease. . . . It enables early detection and treatment in a way that other technologies simply cannot.

As noted above, recent literature on EBT suggests that the use of EBT to better “risk stratify patients could greatly reduce costs and better direct therapy.”

8. The immediate and long-term financial feasibility of the project.

Virginia Imaging states that “[u]tilization of the EBT scanner was conservatively projected, taking into account population in the area and the experience of other similarly-sized markets.” Despite lingering questions regarding future reimbursability, the project should be feasible both immediately and from a long-term perspective, insofar as Syncor International Corporation, which owns Syncor Cardiology Services, which in turn, owns in part Virginia Imaging, had almost \$30,000,000 in net income in 2000.

9. The relationship of the project to the existing health care system of the area in which the project is proposed; however, for projects proposed in rural areas, the relationship of the project to the existing health care services in the specific rural locality shall be considered.

Implementation of Virginia Imaging’s proposal to situate an EBT scanner in Henrico County carries the potential to complement nicely the existing array of advanced cardiological services and medical care in PD 15. Virginia Imaging contends that situating this service outside of any existing hospital, including those of the three major hospital systems in PD 15, renders it more accessible to all patients. The establishment of EBT should not carry the effect of adding CT capacity to a system that has a surplus, and poses little threat of reducing utilization and efficiency at existing providers of CT scans because the EBT scans contemplated will not take the place of, or be interchangeable with, general diagnostic CT scans provided elsewhere.

10. The availability of resources for the project.

Virginia Imaging has adequate financial resources to implement, and likely profit, from this project. The total capital and financing costs are \$2,505,820. Virginia Imaging anticipates that five employees, including a radiological technologist, would be required to staff the project. The human resources necessary would be recruited and should be available.

11. The organizational relationship of the project to necessary ancillary and support services.

Virginia Imaging asserts that the proposed EBT service would be a program unto itself and would not be coordinated with other diagnostic imaging services. However, if an emergent situation arises, the applicant recognizes the need to arrange for the patient’s transfer to another health care facility, such as Henrico Doctors’ Hospital, less than three miles away.

12. The relationship of the project to the clinical needs of health professional training programs in the area in which the project is proposed.

Not applicable.

13. The special needs and circumstances of an applicant for a certificate, such as a medical school, hospital, multidisciplinary clinic, specialty center or regional health service provider, if a substantial portion of the applicant's services or resources or both is provided to individuals not residing in the health service area in which the project is to be located.

Not applicable.

14. The special needs and circumstances of health maintenance organizations. When considering the special needs and circumstances of health maintenance organizations, the Commissioner may grant a certificate for a project if the Commissioner finds that the project is needed by the enrolled or reasonably anticipated new members of the health maintenance organization or the beds or services to be provided are not available from providers which are

not health maintenance organizations or from other health maintenance organizations in a reasonable and cost-effective manner.

Not applicable.

15. The special needs and circumstances for biomedical and behavioral research projects which are designed to meet a national need and for which local conditions offer special advantages.

Not applicable.

16. In the case of a construction project, the costs and benefits of the proposed construction.

Not applicable.

17. The probable impact of the project on the costs of and charges for providing health services by the applicant for a certificate and on the costs and charges to the public for providing health services by other persons in the area.

Approval of the proposed project, due to the very nature of its precise purpose, poses little threat of harmful competition that would increase costs and charges relating to existing providers of CT services. More importantly, the introduction of EBT services to Virginia poses the substantial benefit of diagnosing inchoate coronary disease early, potentially saving the health care system considerable costs in subsequent emergency and high-acuity care.

18. Improvements or innovations in the financing and delivery of health services which foster competition and serve to promote quality assurance and cost effectiveness.

The establishment of EBT in Virginia promises better diagnosis and earlier treatment of coronary artery disease, as well as other conditions. It promises to effectively combat cardiovascular disease and reduce significantly the need for more invasive procedures and high-acuity care. The result should be improved life expectancies for many, better and more effective utilization of

expensive courses of pharmaceutical treatment, and fewer surprise cardiac events. Although these benefits are not the type of improvements and innovation contemplated by this statutory consideration, it is notable, nonetheless.

19. In the case of health services or facilities proposed to be provided, the efficiency and appropriateness of the use of existing services and facilities in the area similar to those proposed, including, in the case of rural localities, any distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.

Although EBT definitionally falls within the ambit of CT technology, and is thereby, a service correctly subject to the requirement of issuing a COPN authorizing its introduction to Virginia, the current surplus of CT capacity in PD 15 ought not be allowed to dictate a denial of a unique form of CT that brings promise in combating cardiovascular disease. EBT should give Virginia physicians an important diagnostic tool that they currently do not have to combat cardiovascular disease. Together with other diagnostic tools, physicians will be better equipped to treat and care for their patients with cardiac disease, and potentially, other diseases and conditions.

20. The need and the availability in the health service area for osteopathic and allopathic services and facilities and the impact on existing and proposed institutional training programs for doctors of osteopathy and medicine at the student, internship, and residency training levels.

Not applicable.

C. RECOMMENDATION

I have reviewed the application and subsequent submissions of Virginia Imaging, LLC, seeking approval for establishment of a medical facility to provide electron beam tomography (EBT), a form of computed tomography (CT). I have heard from Virginia Imaging in support of the application and from the staff of the Division of Certificate of Public Need (DCOPN) who evaluated the proposal. I have considered the recommendation of the board of directors of the Central Virginia Health Planning Agency (CVHPA) which recommended denial of the application.

Virginia Imaging's proposal presents an opportunity to introduce an innovative application of technology – one that has not heretofore existed in Virginia. EBT appears effective in quantifying calcium in the coronary arteries of certain asymptomatic patients at risk for coronary atherosclerosis, thereby carrying the potential to detect cardiac disease, a major cause of death in the U.S., early in its development. Its introduction and implementation may bring additional, perhaps unanticipated, opportunities to benefit public health.

Because EBT scanning for the purpose of quantifying coronary calcium deposits has not been established as reimbursable by public programs and third-party payors, however, its introduction, as proposed, also carries the prospect of providing advanced medical care only to those patients able to afford it. If EBT is to be introduced, it must be done in such a manner as to promote wide access to the benefits it holds. If Virginia Imaging receives authority to embark on this opportunity, it must also agree to honor the public responsibility such an opportunity entails.

Based on my assessment, I have concluded that the proposal merits approval and issuance of a certificate of public need (COPN), due in necessary and fundamental part to Virginia Imaging's agreement to abide by the condition, authorized by Virginia Code Section 32.1-102.2 (C), designed to promote financial access to and charity care involving EBT, and set forth in the attachment to this document.

I make this recommendation fully mindful that, ostensibly, the analysis upon which it rests may appear somewhat inconsistent with some decisions to deny applications for diagnostic imaging made in recent years. I believe, however, that the instant application promises a public benefit altogether different in purpose and effect than a routine application seeking approval of general CT services, and that its approval is fully warranted, despite any initial impression that current CT capacity is adequate to meet the public need. While EBT is CT, CT is not necessarily EBT. I do not believe that the COPN law was designed to be implemented mechanically in all circumstances or intended to thwart an innovative, promising project through the application of specific provisions of the SMFP.

Indeed, the legal doctrine of *stare decisis* is typically understood not to apply normally to administrative decisions. While an agency action must be faithful to whatever authorizing law applies and cannot be unpredictable, the carefully-attenuated application of *stare decisis* to agency actions purposely allows flexibility to act in the public interest without being limited by precedent in the same manner that constitutional and jurisprudential considerations require judicial decisions to be. When an agency's purpose is "regulatory, as distinguished from merely applying law or policy to past facts, an agency must at all times be free to take such steps as may be proper in the circumstances, *irrespective of past decisions*. [Emphasis added.]" 1A Michie's Jurisprudence, Administrative Law § 7 (1993 Repl. Vol.). The present matter, *in toto*, warrants a decision that is cognizant of the broad circumstances involved and considerable benefits presented, as discussed in detail above.

The specific reasons for my recommendation include:

- (i) The proposed project is substantially compliant with the guiding principles of and many applicable standards and provisions contained in the State Medical Facilities Plan (SMFP);
- (ii) The proposed project would introduce a technological innovation in imaging the heart and coronary arteries, such that calcium deposits in the arteries may be identified and quantified early in the progression of coronary artery disease, thereby presenting a substantial advancement in combating heart disease, which directly caused over one-third of all reported deaths in Virginia in 1999;
- (iii) Although EBT is a form of CT, generally-available CT services cannot accomplish the level of detailed and accurate imaging EBT provides;
- (iv) Although planning district (PD) 15 has some underutilized CT capacity, this consideration should not be allowed to effect the denial of a proposal to introduce a specific form of CT that shows considerable promise in improving public health in the Commonwealth;

- (v) Because the project proposed by Virginia Imaging will be tailored mainly to assist cardiologists in diagnosing coronary artery disease, a task that does not routinely involve CT scanning, approval of the project should have no substantial effect on the utilization of existing CT services in PD 15;
- (vi) The proposed project would improve the geographic accessibility to, and the availability of, EBT services for residents of Virginia;
- (vii) The costs of the project proposed by Virginia Imaging are reasonable, and no less costly and more effective alternative presents the benefits EBT promises; and
- (viii) The use of EBT to better determine patients' risk for coronary artery disease should reduce costs and better target therapy, thereby reducing overall health care costs; and
- (ix) Virginia Imaging has agreed to serve the public interest by taking substantial steps toward providing broad access to the benefits EBT promises through a detailed charity and primary care condition, attached to the COPN authorizing this project.

Respectfully submitted,

Douglas R. Harris, J.D.
Adjudication Officer

ATTACHMENT TO
FINDINGS, DISCUSSION
AND RECOMMENDATION
REGARDING
COPN REQUEST NUMBER VA-6635
VIRGINIA IMAGING, L.L.C.

Introduction, Purpose and Context. Virginia Imaging’s proposal presents an opportunity to introduce a promising health care innovation – one that has not heretofore existed in Virginia. Electron beam tomography (EBT), a specific form of computed tomography (CT) and, therefore, a regulated resource under Virginia’s law requiring a certificate of public need (COPN), holds considerable promise in quantifying calcium in the coronary arteries of certain asymptomatic patients at risk for coronary atherosclerosis, thereby carrying the potential to detect cardiac disease, a major cause of death in the U.S., early in its development. EBT may also present benefits in precisely diagnosing gastrointestinal and other conditions.

Because EBT scanning has not been established as generally reimbursable by third-party payors, however, its introduction, as proposed by Virginia Imaging, also carries the prospect of providing advanced medical care only to those patients able to afford it. If EBT is to be introduced in Virginia, it must be done in such a manner as to promote wide access to the benefits it holds for all Virginians.

Notably, African-American males have a considerably greater risk of coronary artery disease than those in the general population and appear to constitute about 15 percent of the population of health planning region (HPR) IV. Also, the percentage of indigent residents in HPR IV is 13.9 percent. (No assumption that the two segments of the population overlap substantially would be accurate and, regardless, such an assumption is not necessary.) If Virginia Imaging is to receive authority to embark on this opportunity, it must agree to honor the public responsibility such an opportunity entails. Without such a commitment, the proposed project lacks complete and compelling merit as an addition to the armamentarium addressing Virginia’s public need for effective health care.

An Effective Charity and Primary Care Condition to Promote Broad Accessibility of EBT Services. Virginia Imaging has expressed “a willingness to provide charity care and to reach out to the community in an effort to assure that the population that can most benefit from EBT services has appropriate access to those services, regardless of ability to pay.” Virginia Imaging’s proposal would merit approval and issuance of a certificate of public need (COPN) if it were to agree to abide by the condition set forth on the following pages, which is designed to promote financial access and charity care and primary care, as authorized by Virginia Code Section 32.1-102.2 (C).

CHARITY AND PRIMARY CARE CONDITION

As authorized by and pursuant to Section 32.1-102.2 (C) of the Virginia Code, issuance of this certificate of public need (COPN) to Virginia Imaging is affirmatively conditioned as provided below.

A. *Specific Charity Care and Primary Care Level and Requirement.* Virginia Imaging will provide:

1. EBT imaging to all indigent persons who need such service, and
 - (a) Are living at or below 100 percent of the Federal non-farm poverty level, at no charge; and
 - (b) Are living at or below 200 percent and above 100 percent of the Federal non-farm poverty level, at an appropriately reduced charge;
2. Contributions to indigent primary care clinics in order to promote the development of primary care; or
3. A combination of 1 and 2, above,

At a total aggregate rate, or value, equal to at least two (2) percent of the annual gross patient revenues Virginia Imaging derives from EBT imaging and services.

B. *Outreach Efforts.*

1. *Existing Resources and Opportunities.* A major obstacle in providing primary care to indigent patients is identifying those patients who need such care, encouraging them to seek services and ensuring that they do so before their health deteriorates to the point of requiring emergency or high-acuity care.

Several hospitals in HPR IV operate parish nurse programs. These programs work through church congregations, using licensed nurses who work to identify patients in need of health care service and refer those patients to appropriate facilities and resources. Parish nurses serve primarily as health educational and reference resources, assisting patients in getting the care they need before their health needs become emergent.

The American Heart Association is currently conducting a community outreach and education program known as Operation Stroke, designed to educate the public about the signs of stroke and to expand access to care for those at risk.

The Central Virginia Health Network – a network of health care providers in the Richmond area – has implemented a program in the eastern portion of the area designed

to identify and promote the treatment of patients at risk of developing diabetes, a disease strongly associated with cardiovascular disease.

2. In order to take advantage of these resources and promote cardiovascular health among indigent Virginians, Virginia Imaging will make verifiable, good faith efforts to:
 - (a) Educate parish nurses and others about EBT, its benefits to the general and indigent patient population, and its availability to indigent patients free of charge or on a reduced-charge basis;
 - (b) Design, implement and coordinate an outreach system with various groups, organizations or resources, such as the parish nurse programs, the American Heart Association, the Central Virginia Health Network, and any other appropriate community or public organization. This outreach system will be specifically designed to promote the identification of patients who may benefit from EBT services, regardless of their ability to pay, to encourage them to seek these services, and to facilitate their actual access to these services, as warranted, by, for example, promoting the transportation of indigent patients for the purpose of receiving EBT services, when needed and practicable;

C. *Educational Efforts.*

1. Virginia Imaging will conduct a series of seminars designed to educate physicians and other health care providers, particularly primary care physicians whose practices consist of providing a substantial amount of care to indigent patients, and health care providers who work in local clinics, about the benefits, purpose and efficacy of EBT scanning. This series will consist of at least nine seminars within the first 12 months of the service's operation, and additional seminars thereafter, as needed.
2. Virginia Imaging will promote general awareness of the existence and open availability of its EBT services, by reasonable and practicable means, among Virginia's physicians. Virginia Imaging will make verifiable efforts to inform various medical specialists, including cardiologists, throughout HPR IV, and elsewhere at its discretion, of the existence, purpose and efficacy of the EBT scanner and imaging facility, and shall make the scanner and facility reasonably available to medical specialists other than cardiologists whose treatment and diagnosis of specific patients may be substantially improved and facilitated by EBT imaging, such as patients with certain gastrointestinal diseases or conditions.

D. *Reporting.* Virginia Imaging will provide to the Virginia Department of Health, Division of Certificate of Public Need (DCOPN) and the Central Virginia Health Planning Agency (CVHPA) an annual written report, audited or otherwise certified by an independent accountant, demonstrating its compliance with and efforts to carry out the requirements set out above and containing information including:

1. The total number of EBT procedures performed during the previous twelve months;
2. The number of EBT procedures performed during that same period free of charge or at a reduced charge; and
3. The value, in dollars, based on the then-current charge for self-paying patients, of free or reduced charge EBT procedures performed during that period.

E. *Development of an Overall Plan.* Virginia Imaging shall provide to DCOPN and CVHPA, prior to initiation of the EBT service but in no event later than October 15, 2002, a written plan setting forth detailed methods for meeting the requirements of the charity and primary care condition, set out above. This plan will become a conspicuous component of any existing or pending business plan, or any business plan to be developed, regarding Virginia Imaging's EBT services.

F. *Cancellation and Replacement of the Charity Care and Primary Care Requirements.* In the event that:

1. EBT procedures become generally reimbursable by third-party payors, as evinced by the portion of EBT revenue from third-party payors exceeding 50 percent of the total annual revenue from the EBT service; or
2. Another health care provider or facility in HPR IV implements an EBT service with capabilities comparable to Virginia Imaging's EBT service;

The charity care and primary care requirements outlined above will be canceled and replaced by a straightforward charity care requirement, *viz.*, one that would require Virginia Imaging to meet or exceed the then-prevailing mean level of net charity care provided by hospitals and health care facilities in HPR IV (calculated so as not to reflect any portion of charity care that a hospital in HPR IV is reimbursed from a state or public fund), expressed as a percentage of gross patient revenues.

Seen and Agreed to:

Laura G. Aaron, Esquire
Counsel to the Applicant,
Virginia Imaging, L.L.C.

Date: April ____, 2002

